JC10 Rec'd PET/PTO 29 JUL 2005

IN THE UNITED TATES PATENT AND TRADEMAR OFFICE

2005 ^{*} | Applicant: Joel Melnick, *et al.*

Serial No.: 10/524,376

Filed: February 15, 2005

For: SHORTENING OF HOSPITAL STAY
AND IMPROVING SURVIVAL IN

PATIENTS WITH CHRONIC

KIDNEY DISEASE

Examiner: (not assigned)

Group Art Unit: (not assigned)

Case No.: 6963.US.01

CERTIFICATE OF MAILING (37 CFR 1.8 (a))

PATENT

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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The following information is submitted, pursuant to 37 CFR §§1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR §1.56. This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR §1.56(a) exists.

Applicants submit herewith Form PTO-1449 listing the references known to them. Applicants respectfully request that the Examiner (1) initial each reference listed on the enclosed Form PTO-1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Form PTO-1449 to Applicants. Copies of all cited documents have been included except any U.S. patent.

No charge is required for the submission of this Information Disclosure Statement under 37 C.F.R. § 1.97 (b). The Commissioner is hereby authorized to charge any additional filing fees required under 37 C.F.R. § 1.17 concerning this transmission, or to credit any overpayment to Deposit Account No. 01-0025.

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Attorney for Applicants

Respectfully submitted,

Joel Melnick, et al

Patricia Coleman James

Registration No. 37,155

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TRANSMITTAL LETTER

Mail Stop Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed herewith is an Information Disclosure Statement for Joel Melnick, *et al.*, for SHORTENING OF HOSPITAL STAY AND IMPROVING SURVIVAL IN PATIENTS WITH CHRONIC KIDNEY DISEASE, the specification of which was filed on February 15, 2005, and received Serial No. 10/524;376.

Also enclosed are:

Form PTO 1449 (in duplicate) w/fourteen (14) references

Return-receipt postcard

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 CFR 1.16, as well as any patent application processing fees under 37 CFR 1.17 associated with this communication for which full payment has not been tendered, to Deposit Account No. 01-0025. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Joel Melnick, et al

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Patricia Coleman James

Registration No. 37,153

Attorney for Applicants

OIAK SC182

DATE:

July <u>25</u>, 2005

SHEET _1_ of _2_

Form PTO - 1449 (Modified

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

6963.US.01

10/524,376

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Joel Melnick, et al.
FILING DATE

GROUP

(Use several sheets if necessary)

February 15, 2005

(not assigned)

(37 CFR 1.98 (b))

U.S.PATENT DOCUMENTS

| EXAMINER INITIAL | PATENT NUMBER | | | | | | | ISSUE PATENTEE | | | | CLASS | ; | SUB CLASS | FILING DATE | |
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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

| C1 | Berweck, S., et al., "Cardiac mortality prevention in uremic patients", Clinical Nephrol 2000 Germany, 53(Suppl1):S80-S85 (2000) |
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| C2 | Cada, D.J., et al., "Paricalcitol Injection and Ribavirin/Interferon Alfa-2b", Hosp. Pharm., Lippincott, Phildelphia, US, 34(3):303-338 (1999) |
| C3 | Drüeke & McCarron, "Paricalcitol as Compared with Calcitriol in Patients Undergoing Hemodialysis", N Engl J Med, 349(5):496-499 (2003) |
| C4 | Keller & Potter, "Predictors of Mortality in Outpatient Geriatric Evaluation and Management Clinic Patients", Journ of Gerontology, 49(6):M246-M251 (1994) |
| C5 | Lanska & Kryscio, "Geographic distribution of hospitalization rates, case fatality, and mortality from stroke in the United States", Neurology, 44(8):1541-1550 (1994) |
| C6 | Lindberg, J., et al., "A long-term, multicenter study of the efficacy and safety of paricalcitol in end-stage renal disease", Clinical Nephrology, 56(4):315-323 (2001) |
| C7 | Llach, F., "Paricalcitol: An Updated Review and Guidelines for Use", <i>Dialysis and Transplantation 2001 US</i> , 30(10) :654-664 (2001) |

EXAMINER DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Form PTO-1449)



DATE:

July <u>25</u>, 2005

SHEET _2_ of _2_

Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

6963.US.01 APPLICANT

10/524,376

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Joel Melnick, et al. FILING DATE

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February 15, 2005

(not assigned)

(37 CFR 1.98 (b))

(Modified)

U.S.PATENT DOCUMENTS

| EXAMINER INITIAL | PATENT NUMBER | | | | | | | ISSUE DATE | PATENTEE | CLASS | SUB CLASS | FILING DATE |
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

| C8 | Marco, M.P., et al., "Influence of Vitamin D Receptor Gene Polymorphisms on Mortality Risk in Hemodialysis Patients", Amer Journ of Kidney Dis, 38(5):965-974 (2001) |
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| C9 | Martin, K.J., et al., "Paricalcitol Dosing According to Body Weight or Severity of Hyperparathyroidism: A Double-Blind, Multicenter, Randomized Study", Amer Journ of Kidney Dis., 38(5)(Suppl5):S57-S63 (2001) |
| C10 | Salusky & Goodman, "Cardiovascular calcification in end-stage renal disease", Nephrol Dial Transplant, 17:336-339 (2002) |
| C11 | Szelachowska, M., et al., "Samoistna Postać zespolu Fanconiego u osoby doroslej", US Natl Libr of Med (NLM), 1(6):414-416 (1996) |
| C12 | Tarantino, G., et al., "The Efficacy of Oral and Intravenous Calcitriol Pulses Therapy in Hemodialysis Patients: Four Years Follou-Up", Nephrology Dialysis Transp., 16(6):A130 (2001) |
| C13 | Teng, M, et al., "Survival Benefit of Zemplar Compared with Calcijex amoung Dialysis Patients", Journ of the Amer Soc of Nephrology, 13 (prog & Abstracts Issue): A461A (2002) |
| C14 | Teng, M., et al., "Survival of Patients Undergoing Hemodialysis with paricalcitol or Calcitriol Therapy", <i>The New Engl Journ of Med.</i> , 349(5) :446-456 (2003) |
| | |

EXAMINER

DATE CONSIDERED

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